

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/580,248 Confirmation No.: 6084
Applicant : Mimi ADACHI, *et al.*
35 U.S.C. § 371 Date : July 20, 2006
Title : METHOD FOR PROLIFERATING CARDIOMYOCYTES
TC/Art Unit : 1632
Examiner: : Magdalene K. Sgagias
Docket No. : 64517.000003
Customer No. : 21967

REQUEST FOR REHEARING UNDER 37 C.F.R. § 41.52

Appellants respectfully request rehearing of the Board's decision mailed September 14, 2011 ("Decision"), in the above-identified matter.

Remarks begin on page 2

REQUEST FOR REHEARING

I. Introduction

In its decision dated September 14, 2011, the Board concluded that the data presented in Appellants' specification was "additive" and did not support a conclusion of unexpected results. The Board did not, however, consider the relative increase in proliferation of the test groups (e.g., D1+CDK4+Skp2, D1+CDK4) compared to the control group. One of ordinary skill in the art would have concluded that, in view of this comparison, Appellants' results are not simply additive, but rather synergistic and unexpected. Accordingly, the USPTO's obviousness rejections should be reversed.

The Board's comments regarding the purported "additive" effect is the first time the USPTO (either the primary examiner or the Board) substantively addressed Appellants' data. Recent case law has reaffirmed that the Board's reliance on facts and rationales not previously raised by the Examiner constitutes a new rejection. Accordingly, in the event the Board does not allow this application, Appellants request a full and fair opportunity to respond to the Board's new rejection in the form of a non-final Official Action.

II. Argument

A. The Board misapprehended Appellants' evidence of unexpected results.

On page 7, lines 3-19 of the Decision, the Board states:

Taken as a whole, the data presented in Appellants' Specification supports a conclusion that the increase in proliferation was additive. The preponderance of evidence on this record supports a conclusion that such an additive increase in proliferation would have been expected by those of ordinary skill in this art ... Accordingly, we are not persuaded by Appellants' contention that their Specification supports a conclusion of unexpected results.

Appellants respectfully submit that the Board misapprehended the data provided in Figure 8.

Example 4 and Figure 8 show the effects on proliferation when (1) a cyclin D and a CDK4 gene; (2) a cyclin gene, a CDK4 gene, and a Skp2 gene; and (3) a Skp2 gene alone are introduced into cardiomyocytes, as compared to a control. As such, the results must be evaluated in view of the proliferation of the control and can be represented as follows:

Group	Increase in Proliferation (observed after 7 days of culture)	Increase in Group Compared to Control (Group - Control) = increase
Control	1.8	0
Skp2	2.0	.2 (i.e., almost no difference)
D1+CDK4	3.2	1.4
D1+CDK4+Skp2	5.3	3.5

In view of these results, one of ordinary skill in the art would conclude (1) that there is a significant difference between the D1+CDK4+Skp2 group and D1+CDK4 group, when these groups are compared to the control; and (2) the effect produced by the combination of D1+CDK4+Skp2 is not simply additive, but rather synergistic and unexpected.¹ The Board's own review of the art shows that the Board viewed the "expected" results as merely achievement of an additive effect, not the synergistic effect achieved by Appellants. Accordingly, because the Board misinterpreted Appellants' evidence of unexpected results, Appellants' respectfully request that this rejection be withdrawn.

B. Recent case law mandates that the Board reverse this case.

Appellants' presented and discussed the results of Examples 4 and 5 throughout

¹ One of ordinary skill in the art would conclude the same regarding the results described in Example 6 and Figure 10.

prosecution.² The Examiner never substantively addressed these results, let alone assert that the increase in proliferation was merely additive. Rather, at best, the Examiner only suggested that the specification should have provided a different comparison.³ Accordingly, the Board's decision is the first time the USPTO analyzed Appellants' data and asserted that the results were not unexpected.

The U.S. Court of Appeals for the Federal Circuit has recently reversed two Board decisions where the Board (1) relied on facts and rationales not previously before the Appellant (i.e., the Board made a new rejection); and (2) did not provide Applicant a full and fair opportunity to respond to the new rejection. Both cases were decided after the instant Board decision.

In *In re Stepan Company*,⁴ Applicant's claims were rejected as being obvious over a reference by Singh. Applicant filed a Rule 131 Declaration to antedate Singh. Because the examiner erroneously believed that the Singh reference was a 102(b) reference, the Examiner never addressed the sufficiency of the Rule 131 Declaration. The Board, however, found that Singh was a 102(a) reference, which could be overcome with a 131 Declaration, but nonetheless concluded that the Declaration filed by Applicant was insufficient. Because the Examiner never questioned the sufficiency of the Declaration, Applicant argued that it never had the opportunity to respond to the deficiencies first identified by the Board.

² See, e.g., Response filed November 13, 2007, pages 8 and 9; Response filed July 28, 2008, page 9; Response filed October 10, 2010, page 7; Appeal Brief filed November 19, 2009, pages 10-12 and 14; Reply Brief, pages 7 and 8.

³ See Reply Brief, page 8 (citing Examiner's Answer, page 7 ("Applicants have not provided evidence that following co-expression of Skp2, cyclin D, and CDK4 would not result in increased cell proliferation as compared to expression of these genes alone in cardiomyocytes."))

⁴ 100 U.S.P.Q.2d 1489 (Fed. Cir. 2011).

The Federal Circuit agreed. The court held that because the Board made and relied on new fact findings regarding an issue the Examiner did not raise, the Board relied on a new ground of rejection.⁵ Moreover, the court stated:

Mere reliance by the Board on the same type of rejection or the same prior art references relied upon by the Examiner, alone, is insufficient to avoid a new ground of rejection where it propounds new facts and rationales to advance a rejection—none of which were previously raised by the Examiner.⁶

In *In re Leithem*,⁷ the Examiner asserted that a reference by Novak taught a “fluff pulp.” Applicant argued that Novak’s pulp was not fluffed. The Board agreed with Applicant, but affirmed the Examiner’s rejection by finding that Novak teaches a pulp “which may be fluffed.” The Federal Circuit held that the Board found new facts concerning the prior art, the Board’s rejection relied on these facts, and Applicant would have responded differently had the Examiner’s original rejection recited the Board’s interpretation of Novak.⁸ Accordingly, because Applicant was not given an opportunity to respond to the Board’s new rejection, the court reversed the Board’s decision.⁹

In the instant case, as with those cited above, the Board likewise propounded new facts and rationales to advance a rejection, none of which were previously raised by the Examiner. The Board’s reliance on new facts and rationales concerning Appellants’ data would, in view of the Federal Circuit’s recent case law, be considered “*a new ground of rejection*.” Appellants have not had an opportunity to respond to this new ground of rejection. Accordingly, if the Board does not allow this application, then Appellants respectfully request a full and fair opportunity to respond to the Board’s new rejection.

⁵ *Id.* at 1492.

⁶ *Id.* at 1491.

⁷ 100 U.S.P.Q.2d 1155 (Fed. Cir. 2011).

⁸ *Id.* at 1159.

⁹ *Id.* at 1160.

III. Conclusion

The Board misapprehended Appellants' data. Properly interpreted, this data demonstrates that the introduction of (a) a cyclin; (b) a cyclin-dependent kinase; and (c) a gene encoding a factor that inhibits the production or function of a Cip/Kip protein into a cardiomyocyte provides an unexpected increase in proliferation. Accordingly, Appellants' respectfully request that the obviousness rejections be withdrawn.

In addition, Appellants respectfully submit that the Board's decision makes a new rejection. As such, Appellants should be afforded the full and fair opportunity to respond to the new rejection.

Respectfully submitted,
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Date: November 14, 2011

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